

§ 158.320

40 CFR Ch. I (7–1–12 Edition)

(f) *Test notes.* The following test notes are applicable to the product chemistry data requirements in the table to paragraph (e) of this section:

1. Data must be provided in accordance with § 158.320.
2. Data must be provided in accordance with § 158.325.
3. Data must be provided in accordance with § 158.330.
4. Data must be provided in accordance with § 158.335.
5. Data must be provided in accordance with § 158.340.
6. Data must be provided in accordance with § 158.345.
7. Data must be provided in accordance with § 158.350.
8. Data must be provided in accordance with § 158.355.
9. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI.
10. Data are required if the product is produced by an integrated system.
11. Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end-use products produced by an integrated system must be submitted on a case-by-case basis.
12. Data on the stability to metals and metal ions are required only if the TGAI is expected to come into contact with either material.
13. Required when the product contains an oxidizing or reducing agent.
14. Required when the product contains combustible liquids.
15. Required when the product is potentially explosive.
16. Required when the product is an emulsifiable liquid and is to be diluted with petroleum solvent.
17. Required when the EP is a liquid and is to be used around electrical equipment.
18. Required when the test substance is soluble or dispersible in water.
19. Required when the product is a liquid.
20. Required when the TGAI is solid at room temperature.
21. Required when the TGAI is liquid at room temperature.
22. Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).
23. Required for water insoluble test substances ($>10^{-6}$ g/l) and fibrous test substances with diameter of ≥ 0.1 μm .

24. Required if technical chemical is organic and non-polar.

25. Not required for salts.

26. Data on stability of the MP and TGAI to storage at normal temperatures are required. Data on the stability of the TGAI to high temperatures are required if the TGAI is expected to be subjected to temperatures >50 °C (122 °F) during production or storage.

§ 158.320 Product identity and composition.

Information on the composition of the pesticide product must be furnished. The information required by paragraphs (a), (b), and (f) of this section must be provided for each product. In addition, if the product is produced by an integrated system, the information on impurities required by paragraphs (c) and (d) of this section must be provided.

(a) *Active ingredient.* The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product:

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product.

(ii) The nominal concentration of the active ingredient in the product, based upon the nominal concentration of active ingredient in the source product.

(iii) Upper and lower certified limits of the active ingredient in the product, in accordance with § 158.350.

(2) If the source of any active ingredient in the product is not an EPA-registered product:

(i) The chemical name according to Chemical Abstracts Society (CAS) nomenclature, the CAS Registry Number, and any common names.

(ii) The molecular, structural, and empirical formulae and the molecular weight or weight range.

(iii) The nominal concentration.

(iv) Upper and lower certified limits of the active ingredient in accordance with § 158.350.

(v) The purpose of the ingredient in the formulation.

(b) *Inert ingredients.* The following information is required for each inert ingredient (if any) in the product:

(1) The chemical name of the ingredient according to Chemical Abstracts

Society nomenclature, the CAS Registry Number, and any common names (if known). If the chemical identity or chemical composition of an ingredient is not known to the applicant because it is proprietary or trade secret information, the applicant must ensure that the supplier or producer of the ingredient submits to the Agency (or has on file with the Agency) information on the identity or chemical composition of the ingredient. Generally, it is not required that an applicant know the identity of each ingredient in a mixture that he uses in his product. However, in certain circumstances, the Agency may require that the applicant know the identity of a specific ingredient in such a mixture. If the Agency requires specific knowledge of an ingredient, it will notify the applicant in writing.

(2) The nominal concentration.

(3) Upper and lower certified limits in accordance with § 158.350.

(4) The purpose of the ingredient in the formulation.

(c) *Impurities of toxicological significance associated with the active ingredient.* For each impurity associated with the active ingredient that is determined by EPA to be toxicologically significant, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the product.

(4) A certified upper limit, in accordance with § 158.350.

(d) *Other impurities associated with the active ingredient.* For each other impurity associated with an active ingredient that was found to be present in any sample at a level ≥ 0.1 percent by weight of the technical grade active ingredient the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the final product.

(e) *Impurities associated with an inert ingredient.* [Reserved]

(f) *Ingredients that cannot be characterized.* If the identity of any ingredient or impurity cannot be specified as a discrete chemical substance (such as mixtures that cannot be characterized or isomer mixtures), the applicant must provide sufficient information to enable EPA to identify its source and qualitative composition.

§ 158.325 Description of materials used to produce the product.

The following information must be submitted on the materials used to produce the product:

(a) *Products not produced by an integrated system.* (1) For each active ingredient that is derived from an EPA-registered product:

(i) The name of the EPA-registered product.

(ii) The EPA registration number of that product.

(2) For each inert ingredient:

(i) Each brand name, trade name, common name, or other commercial designation of the ingredient.

(ii) All information that the applicant knows (or that is reasonably available to him) concerning the composition (and, if requested by the Agency, chemical and physical properties) of the ingredient, including a copy of technical specifications, data sheets, or other documents describing the ingredient.

(iii) If requested by the Agency, the name and address of the producer of the ingredient or, if that information is not known to the applicant, the name and address of the supplier of the ingredient.

(b) *Products produced by an integrated system.* (1) The information required by paragraph (a)(1) of this section concerning each active ingredient that is derived from an EPA-registered product (if any).

(2) The following information concerning each active ingredient that is not derived from an EPA-registered product:

(i) The name and address of the producer of the ingredient (if different from the applicant).

(ii) Information about each starting material used to produce the active ingredient, as follows: